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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/014,096	02/04/93	HUSTON	J CRP-008DV (20

PATENT ADMINISTRATOR
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HM12/1127

EXAMINER

ULM, J

ART UNIT

PAPER NUMBER

1646

31

DATE MAILED:

11/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/014,096

Applicant(s)
Huston et al.

Examiner
John Ulm

Group Art Unit
1646



☒ Responsive to communication(s) filed on Sep 20, 1994

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 47-53, 56-61, and 63-68 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 47-49, 51-53, 56-61, and 63-68 is/are rejected.

☒ Claim(s) 50 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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- 1) Claims 47 to 53, 56 to 61 and 63 to 68 are pending in the instant application.
- 2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4) The instant application has been remanded to the examiner of record by the Board of Patent Appeals and Interferences for further prosecution on the merits.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

- 5) Claims 47 to 49, 51 to 53, 56 to 59 and 63 to 68 are rejected under 35 U.S.C. 102(e) as being anticipated by the Cousens et al. patent (4,741,180) in view of Löfdahl et al. (WO 84/03103, 16 Aug. 1984) and Lehninger (Biochemistry, 1978, Worth Publishing, pages 130-131). The Cousens et al. patent issued from application Serial Number 06/845,737, filed 28 March of 1986 as a continuation in part of application Serial Number 06/717,209, filed 28 March of 1985. These claims encompass the two fusion proteins which were described on page 15 of the Cousens et al. '209 application as "GAP_p M BCA5 KRSTS PYK PYK_i" and "GAP_p M BCA5 KR(ST)₂S SOD GAP_i". These two fusion proteins are also described in TABLE 1 of the

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Cousens et al. patent. Each of these two fusion proteins comprised a first and second polypeptide joined to one another by a flexible linker containing a proteolytic cleavage site. The flexible nature of the linker was an inherent property thereto as was the fact that it facilitated cleavage of those two polypeptides by a protease. M.P.E.P. 2112 states as follows

Requirements of Rejection Based on Inherency; Burden of Proof

The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." In re Napier, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995)(affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also In re Grasselli, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product by process claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103.

A REJECTION UNDER 35 U.S.C. 102 / 103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102 / 103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic.

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Therefore, 35 U.S.C. 102 / 103 rejection is appropriate for these types of claims as well as for composition claims.

EXAMINER MUST PROVIDE RATIONALE OR EVIDENCE TENDING TO SHOW
INHERENCY

>The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert , 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)(reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich , 666 F.2d 578, 581 - 82, 212 USPQ 323, 326 (CCPA 1981).<

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented . It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." Id. at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

ONCE A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily >or inherently< possess the characteristics of his [or her] claimed product. ***Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly

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or alternatively, the burden of proof is the same.>..[footnote omitted].<" The burden of proof is similar to that required with respect to product - by - process claims. In re Fitzgerald**>619 F. 2d 67, 70,< 205 USPQ 594,>596< (CCPA 1980) (quoting **>In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 - 34 (CCPA 1977)<).

In In re Fitzgerald **, 205 USPQ 594 (CCPA 1980), the claims were directed to a self - locking screw - threaded fastener comprising a metallic threaded fastener having patches of crystallizable thermoplastic bonded thereto. The claim further specified that the thermoplastic had a reduced degree of crystallization shrinkage. The specification disclosed that the locking fastener was made by heating the metal fastener to melt a thermoplastic blank which is pressed against the metal. After the thermoplastic adheres to the metal fastener, the end product is cooled by quenching in water. The examiner made a rejection based on a U.S. patent to Barnes. Barnes taught a self - locking fastener in which the patch of thermoplastic was made by depositing thermoplastic powder on a metallic fastener which was then heated. The end product was cooled in ambient air, by cooling air or by contacting the fastener with a water trough. The court first noted that the two fasteners were identical or only slightly different from each other. "Both fasteners possess the same utility, employ the same crystallizable polymer (nylon 11), and have an adherent plastic patch formed by melting and then cooling the polymer." Id. at 596 n.1. The court then noted that the Board had found that Barnes' cooling rate could reasonably be expected to result in a polymer possessing the claimed crystallization shrinkage rate. Applicant had not rebutted this finding with evidence that the shrinkage rate was indeed different. They had only argued that the crystallization shrinkage rate was dependent on the cool down rate and that the cool down rate of Barnes was much slower than theirs. Because a difference in the cool down rate does not necessarily result in a difference in shrinkage, objective evidence was required to rebut the 35 U.S.C. 102 / 103 prima facie case.

See MPEP § 2113 for more information on the analogous burden of proof applied to product - by - process claims.

2112.01 Composition, Product, and Apparatus Claims [R - 1]

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>PRODUCT AND APPARATUS CLAIMS - WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 195 USPQ 430, 433 (CCPA 1977).

See also Titanium Metals Corp. v. Banner, 227 USPQ 773 (Fed. Cir. 1985) (Claims were directed to a titanium alloy containing 0.2 - 0.4% Mo and 0.6 - 0.9% Ni having corrosion resistance. A Russian article disclosed a titanium alloy containing 0.25% Mo and 0.75% Ni but was silent as to corrosion resistance. The Federal Circuit held that the claim was anticipated because the percentages of Mo and Ni were squarely within the claimed ranges. The court went on to say that it was immaterial what properties the alloys had or who discovered the properties because the composition is the same and thus must necessarily exhibit the properties.);

In re Ludtke, 169 USPQ 563 (CCPA 1971) (Claim 1 was directed to a parachute canopy having concentric circumferential panels radially separated from each other by radially extending tie lines. The panels were separated "such that the critical velocity of each successively larger panel will be less than the critical velocity of the previous panel, whereby said parachute will sequentially open and thus gradually decelerate." The court found that the claim was anticipated by Menget. Menget taught a parachute having three circumferential panels separated by tie lines. The court upheld the rejection finding that applicant had failed to show that Menget did not possess the functional characteristics of the claims.);

Northam Warren Corp. v. D. F. Newfield Co., 7 F.Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) (A patent to a pencil for cleaning fingernails was held invalid because a pencil of the same structure for writing was found in the prior art.).

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COMPOSITION CLAIMS - IF THE COMPOSITION IS PHYSICALLY THE SAME, IT
MUST HAVE THE SAME PROPERTIES

"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada , 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty.").<

The text in lines 23 to 35 in column 4 of the Cousens et al. patent shows that a linker of at least two amino acids in length and which is composed of only serine and threonine residues is expected to be flexible. The text in the first paragraph on page 19 of the instant specification indicates that such a linker would be expected to be flexible and to facilitate proteolytic cleavage of a fusion protein if positioned next to an endopeptidase cleavage site, as was the linker of Cousens et al. Therefore, the instant specification supports a conclusion that those two fusion proteins of Cousens et al. inherently meet all of the limitations of the instant claims.

The pages 130 and 131 from the biochemistry textbook by Lehninger, and Table 6-1 contained therein, have been cited because they show that an artisan of ordinary skill in the art of molecular biology would have immediately recognized the flexible nature of the serine-threonine linker employed by Cousens et al. Whereas the Cousens et al. '209 application did not expressly disclose the flexible nature of the linkers employed therein, an application is not required to teach that which was well known in the art at the time that it was filed. It is sufficient that those linkers

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were inherently flexible and that an artisan would have recognized that fact from nothing more than a knowledge of their amino acid sequences.

The Löfdahl et. al. reference has been cited because text in lines 32 to 34 on page 6 of that. reference taught that "[o]ften it may be preferred to use chemical cleaving agents" to cleave a fusion protein "because protease recognition sequences may be sterically hindered in the produced fused protein". This reference shows that an artisan was well aware that steric hindrance could prevent a protease from cleaving a fusion protein whereas steric hindrance was not considered an obstacle to the cleavage of a fusion protein by a chemical cleavage agent. This reference is relevant because the Cousens et al. '209 application actually described five fusion proteins in the examples contained therein. Two of those proteins contained protease cleavage sites between the two components of the fusion protein whereas three of them contained chemical cleavage sites. Only the two fusion proteins containing the protease cleavage sites contained serine-threonine linkers and those linkers were directly adjacent to protease cleavage sites which had been incorporated therein. Therefore, an artisan, in view of nothing more than the disclosure of the five fusion proteins described in the Cousens et al. '209 application would have immediately recognized the flexible nature of the serine-threonine linkers employed in two of those proteins and would have appreciated the fact that those linkers were included only in the fusion proteins containing protease cleavage sites to facilitate the cleavage of those two proteins by relieving the potential steric hindrance which would have otherwise prevented the protease from reaching the cleavage site within those proteins.

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6) Claims 60 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Cousens et al. patent (4,741,180) in view of Löfdahl et al. (WO 84/03103, 16 Aug. 1984) and Lehninger (Biochemistry, 1978, Worth Publishing, pages 130-131). as applied to claims 47 to 49, 51 to 53, 56 to 59 and 63 to 68 above, and further in view of the Cohen et al. patent (4,743,679). These claims differ from those above in requiring a cleavage site for *Staphylococcus aureus* V-8 protease. The text in lines 12 to 25 on page 6 of Löfdahl et al. essentially teaches that any protease can be employed to cleave a fusion protein provided that a cleavage site for that protease has been incorporated at the junction of the components of that fusion protein and provided that such a site does not occur within the desired protein. The Cohen et al publication shows that the incorporation of a cleavage site for *S. aureus* V-8 protease at the junction of the components of that fusion protein to facilitate the cleavage of that protein by *S. aureus* V-8 protease was known and practiced in the art prior to the making of the instant invention.

7) Claim 50 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. There was no motivation to incorporate a proline residue into a flexible linker like that of Cousens et al. since it was well known in the art at that time that the presence of a proline residue in such a linker would have created a "rigid kink" in that linker, as disclosed on page 131 of the Lehninger reference.

8) Applicant's arguments filed 20 September of 1994 have been considered but are moot in view of the new ground(s) of rejection.

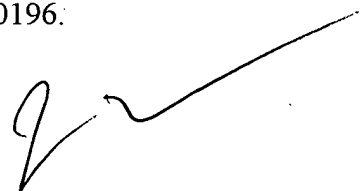
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800